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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,539	01/11/2002	Ambrose L. Cheung	DC-0199	7285
7590 12/03/2003		EXAMINER		
Pennie & Edmonds LLP 1155 Avenue of the Americas			SHAHNAN SHAH, KHATOL S	
New York, NY 10036-2711			ART UNIT	PAPER NUMBER
			1645	
			DATE MAILED: 12/03/2003	3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary    Examiner	(a) 3	Application No.	Applicant(s)					
Kinatol S Shahnan-Shah   1645								
The MAILING DATE of this communication appears on the cover sheet with the correspondence address → Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of the major be willout earlier by existed and the state of the common of 3° CPR 1.786(). In relevent, however, may a reply be timely filled state in St. 69 JACKTYSS time the realisting date of this common of 3° CPR 1.786(). In relevent, however, may a reply be timely filled state in St. 69 JACKTYSS time the realisting date of this common of the	Office Action Summary	Examiner	Art Unit					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \$\frac{t}{2}\] MONTH(\$) FROM THE MAILING DATE OF THIS COMMUNICATION.								
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2a)  This action is FINAL. 2b)  This action is non-final.  3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s)	<ul> <li>THE MAILING DATE OF THIS COMMUNICATION.</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>							
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	2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) 🔲 Notice of Informal P						

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-6 are, drawn to DNA, vector and host cell, classified in classes 536 and
     435, subclasses 23.1 and 252.3.
  - II. Claims 7-12 are, drawn to a method of identifying an agent which inhibits growth of bacteria and a method of inhibiting growth, classified in class 453, subclass 32.
  - III. Claims 13-16 are, drawn to a pharmaceutical composition, classified in class 536, subclass 23.7.
  - IV. Claims 17-19 are, drawn to a polypeptide, classified in class 530, subclass 300.
  - V. Claim 20 is, drawn to a kit for identifying the presence of a gene, classified in class 435, subclass 6.
  - VI. Claims 21 and 27 are, drawn to a pharmaceutical composition and a method of treating a mammal by using a compound capable of selective occupation of a receptor, classified in class 514, subclass 44.
  - VII. Claims 22-25 are, drawn to pharmaceutical compositions and methods of screening, classified in class 514, subclass 2.
- 2. The inventions are distinct, each from the other because of the following reasons:

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Groups I, III, IV and V are distinct because claims of groups I, III, IV and V are drawn to distinct products. The inventions are shown to be distinct because they are drawn to materially and structurally distinct products.

Inventions II, VI and VII are drawn to different methods. The inventions are shown to be distinct because they are drawn to distinct methods, which differ in method objectives, method steps, reagents and material used.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case DNA of group I can be used in PCR.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case protein of group I can be used in PCR.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I (a DNA) and group V (a kit identifying a gene) are not related to each other.

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Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of group II is not needed for a process of group VI.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. The several inventions above are independent and distinct, each from the other for the reasons stated. They have also acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. The search of each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or make obvious the any of the other groups.
- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-

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8896. The examiner can normally be reached on 7:30 AM - 4 PM from Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization

where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

**Biotechnology Patent Examiner** 

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November 28, 2003

RODNEY P SWARTZ, PH.D PRIMARY EXAMINER